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Dean Burfoot

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EXAMINER

MILLER HARRIS, AMBER R

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No. 10/529,402	Applicant(s) BURFOOT, DEAN	
	Examiner AMBER MILLER HARRIS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 2,6,9,15 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/06/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2008 has been entered.

Claim Objections

1. Claims 2, 6, 9, 15, and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims provide the method of using the sterile trolley and do not further limit the apparatus.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 4-12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howorth US 4,531,956 in view of Lin et al. US 6,694,892 and Von Otto US 3,881,477.

4. For claim 1, the Howorth reference discloses a sterile air trolley comprising a mobile casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and column 2, lines 46-49), the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects 22 a and b), forming a continuously replenished rising layer of filtered air over the work surface. The reference does not disclose the work surface having an upstanding boundary wall extending around its perimeter whereby

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the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface.

5. The Lin et al. reference discloses the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface (figure 4, objects 22 and 23).

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall forming a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface whereby (Lin et al. figure 4, objects 22 and 23) because this allows for the objects to be sterilized to be securely within the apparatus and allows the all over flow of sterilized air.

7. The Von Otto reference discloses the walls emitting filtered air on all sides (Von Otto figure 1 object A).

8. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to disclose the boundary walls emitting filtered air on all sides (Von Otto figure 1 object A) because this allows the sterilized air to completely surround the opening.

9. For claim 2, the Howorth reference discloses the need for all over flow of sterilized air from the work surface, and forming a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume (figure 2 objects 22 a

and 22b). The reference does not disclose the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall.

10. The Lin et al. reference discloses a work surface having boundary walls (figure 3 object 22).

11. It would be obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface having boundary walls (Lin et al. figure 3 object 22) because this allows for the objects to be sterilized to be securely within the apparatus and allows the all over flow of sterilized air.

12. The Von Otto reference discloses having the walls having outlets on all sides and therefore filtered air being emitted inwardly over the work surface from all four sides (Von Otto figure 1 object A).

13. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to disclose the boundary walls emitting filtered air on all sides (Von Otto figure 1 object A) because this allows the sterilized air to completely surround the opening.

14. For claim 4, the Howorth reference discloses filtered air being emitted from the work tray on all sides (figure 2 objects 22 a and b). The reference does not disclose the all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle.

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15. The Lin et al. reference discloses all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle (figure 2 objects 20 and 22).

16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle (Lin et al. figure 2 objects 20 and 22) because this allows for the objects to be sterilized to be securely within the working tray.

17. For claim 5, the Howorth reference discloses the trolley casing is in a modular form having a base unit housing the impeller and an upper unit comprising the work surface (figures 1 objects 11 and 12, and figure 2 object 17). The reference does not disclose the work surface being tray-shaped with a boundary wall, and the upper unit being readily demountable from and re-mountable to the base unit.

18. The Lin et al. reference discloses the work surface being tray-shaped with a boundary wall (figure 2 objects 20 and 22).

19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface being tray-shaped with a boundary wall (Lin et al. figure 2 objects 22 and 20) because this allows for the objects to be securely within the working tray.

20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the upper unit being readily demountable from and re-mountable to the base unit, since it has been held that constructing a formerly integral

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structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

21. For claim 6, the Howorth reference does not disclose sterilized surgical instruments are set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface.

22. The Lin et al. reference discloses a tray that has the ability to have sterilized surgical instruments on the top of the surface, and to mount foil or a lid on the top of the tray (figure 2 objects 20 and 22). It would have been within the skill of one having ordinary skill in the art at the time the invention was made to have modified the Lin et al. reference to include the ability to mount foil or a lip on the top of the tray in order to keep the trays contents free of dust.

23. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include sterilized surgical instruments set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface (figure 2 objects 20 and 22) because this allows for the objects to be securely within the tray, and the contents of the tray to be free of dust.

24. For claims 7 and 8, the Howorth reference discloses the need for a working tray to put surgical instruments or other items place flat on the working surface (3-16). The reference discloses that the working tray could have any dimension (column 3, lines 20-24). The reference does not disclose the working surface being a rectangular tray with boundary walls higher than the instruments, the height of the boundary wall is slightly

greater than the height of the any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud the same, and the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air.

25. The Lin et al. reference discloses a rectangular tray with boundary walls that would be higher than the surgical instruments (figure 2 objects 20 and 22). The reference does not disclose the surgical instruments. It would be obvious to one having ordinary skill in the art at the time the invention was made that the boundary wall being higher than a human shoulder (figure 5 object 22) would also be higher than surgical instruments laying flat. The reference does not disclose the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

26. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth et al. reference to include the working surface being a rectangular tray with boundary walls higher than the instruments, the height of the boundary wall is slightly greater than the height of the any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud the same, and the height of the boundary wall is on the order of 200 to

300mm while maintaining the blanket of sterile air (Lin et al. figure 2 objects 20 and 22 and figure 5 object 22) because this allows for the objects to be securely within the tray.

27. For claim 9, the Howorth reference does not disclose the rate of flow of air from the outlets is of the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second.

28. The Lin et al. reference discloses the rate of flow of air from the outlets is of the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second (column 3, lines 60-61).

29. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the rate of flow of air from the outlets is of the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second (Lin et al. column 3, lines 60-61) because this provides laminar air flow.

30. For claim 10 the Howorth et al. reference discloses the work tray being densely perforated with many substantially uniform distributed apertures to provide a substantially uniform flow of air through the work tray (figure 2 objects 22 a, b and 15). The reference does not disclose the work tray comprising boundary walls.

31. The Lin et al. reference discloses the work tray comprising boundary walls (figure 2 objects 20 and 22).

32. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work tray

comprising boundary walls (figure 2 objects 20 and 22) because this allows for the objects to be securely within the tray.

33. For claim 11, the Howorth reference does not explicitly state the construction of the part of the boundary wall comprising the outlets is such as to provide a pressure drop of the order of at least 10 Pascal's. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the construction of the part of the boundary wall comprising the outlets is such as to provide a pressure drop of the order of at least 10 Pascal's, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

34. For claim 12, the Howorth reference discloses a sterile air trolley having a sterile air cabinet comprising a casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and column 2, lines 46-49), the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects 22 a and b), forming a continuously replenished rising layer of filtered air over the work surface. The reference does not disclose the work surface having an upstanding boundary wall extending around its

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perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface.

35. The Lin et al. reference discloses the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface (figure 4, objects 22 and 23).

36. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface whereby (Lin et al. figure 4, objects 22 and 23) because this allows for the objects to be sterilized to be securely within the apparatus.

37. The Von Otto reference discloses the walls emitting filtered air on all sides (Von Otto figure 1 object A).

38. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to disclose the walls emitting filtered air on all sides (Von Otto figure 1 object A) because this allows the sterilized air to completely surround the opening.

39. For claim 14, the Howorth reference discloses a sterile air trolley comprising a mobile casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and

enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and column 2, lines 46-49), the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects 22 a and b), forming a continuously replenished rising layer of filtered air over the work surface. The reference does not disclose the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface, and the air outlets facing only substantially inwardly towards the work surface from the boundary wall.

40. The Lin et al. reference discloses the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface (figure 4, objects 22 and 23).

41. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface having an upstanding boundary wall extending around its perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface whereby (Lin et al. figure 4, objects 22 and 23) because this allows for the objects to be sterilized to be securely within the apparatus.

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42. The Von Otto reference discloses the wall emitting filtered air, the air outlets facing substantially inwardly from the boundary walls towards the work surface, (Von Otto figure 1 object A).

43. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to disclose the walls emitting filtered air on all sides (Von Otto figure 1 object A) because this allows the sterilized air to completely surround the opening.

44. For claim 15, the Howorth reference discloses the need for all over flow of sterilized air from the work surface, and forming a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume (figure 2 objects 22 a and 22b). The reference does not disclose the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall.

45. The Lin et al. reference discloses a work surface having boundary walls (figure 3 object 22).

46. It would be obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface having boundary walls (Lin et al. figure 3 object 22) because this allows for the objects to be sterilized to be securely within the apparatus.

47. The Von Otto reference discloses the walls having outlets on all sides, and therefore filtered air being emitted inwardly over the work surface from all four sides (Von Otto figure 1 object A).

48. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to disclose the walls having outlets on all sides, and therefore filtered air being emitted inwardly over the work surface from all four sides (Von Otto figure 1 object A) because this allows the sterilized air to completely surround the opening.

49. For claim 16, the Howorth reference discloses filtered air being emitted from the work tray on all sides (figure 2 objects 22 a and b). The reference does not disclose the all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle.

50. The Lin et al. reference discloses all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle (figure 2 objects 20 and 22).

51. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle (Lin et al. figure 2 objects 20 and 22) because this allows for the objects to be sterilized to be securely within the working tray.

52. For claim 17, the Howorth reference discloses the trolley casing is in a modular form having a base unit housing the impeller and an upper unit comprising the work

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surface (figures 1 objects 11 and 12, and figure 2 object 17). The reference does not disclose the work surface being tray-shaped with a boundary wall, and the upper unit being readily demountable from and re-mountable to the base unit.

53. The Lin et al. reference discloses the work surface being tray-shaped with a boundary wall (figure 2 objects 20 and 22).

54. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface being tray-shaped with a boundary wall (Lin et al. figure 2 objects 22 and 20) because this allows for the objects to be securely within the working tray.

55. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the upper unit being readily demountable from and re-mountable to the base unit, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrrnan*, 168 USPQ 177, 179.

56. For claim 18, the Howorth reference does not disclose sterilized surgical instruments are set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface.

57. The Lin et al. reference discloses a tray that has the ability to have sterilized surgical instruments on the top of the surface, and to mount foil or a lid on the top of the tray (figure 2 objects 20 and 22). It would have been within the skill of one having ordinary skill in the art at the time the invention was made to have modified the Lin et al.

reference to include the ability to mount foil or a lip on the top of the tray in order to keep the trays contents free of dust.

58. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include sterilized surgical instruments are set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface (figure 2 objects 20 and 22) because this allows for the objects to be securely within the tray, and the contents of the tray to be free of dust.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER MILLER HARRIS whose telephone number is (571)270-3149. The examiner can normally be reached on Mon-Thur (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AH

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797